

**REMARKS****I. Introduction**

This paper is submitted in response to the Office Action mailed February 18, 2004. Claims 2-6, 8, 10-17, 19, 23 and 28-35 were cancelled. Claims 1, 7, 9, 18, 20-22, 24-27, 36 and 37 are pending. The Office Action stated that Claims 1, 7, 21, 24 and 26 are allowable. Claims 9, 18, 20, 22, 25, 27, 36 and 37 were rejected. Claims 9, 18, 20, 36 and 37 have been amended, as discussed below. Support for the amendments to the claims can be found throughout the specification and claims as originally filed. In particular, support for the amendments to claims 18, 20 and 36 can be found in the specification as originally filed at page 2, line 30 - page 3, line 17. Support for the amendment to claim 9 can be found in the specification as originally filed at page 2, lines 30-36. Support for the amendment to claim 37 can be found in the specification as originally filed at page 2, lines 6-23. There is no new matter added as a consequence of the amendments to the claims.

**II. The Rejections under 35 U.S.C. § 112, ¶1 Should Be Withdrawn**

The Examiner has rejected claims 9, 22, 25, 27 and 36 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement because the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors possessed the claimed invention at the time the application was filed. Specifically, the Examiner alleges that the sections of the specification cited in the amendment dated September 22, 2003 do not provide

support for the limitation in claim 9: “any second *P. aeruginosa* protein or a fragment of said second protein.” *See Office Action* § 19.

Applicants respectfully disagree. An applicant may show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e. complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. *Guidelines for Examination of Patent Application Under the 35 U.S.C.*, ¶1, “Written Description” Requirement. 66 FR 1099, 1106. Nevertheless, Applicants have amended claim 9 to recite the limitation, “a second protein or a fragment of said second protein wherein said second protein is a *P. aeruginosa* antigen.” Accordingly, Applicants respectfully request that the rejection of claim 9 under 35 U.S.C. § 112, first paragraph be withdrawn. Since claims 22, 25, 27 and 36 depend from claim 9, and only claim 9 was addressed in this rejection, Applicants respectfully request that the rejections of claims 22, 25, 27 and 36 be withdrawn as well.

### **III. The Rejections under 35 U.S.C. § 112, ¶2 Should Be Withdrawn**

The Examiner has rejected claims 9, 18, 20, 22, 25, 27 and 36 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner alleges that claims 18, 20 and 36 are vague and indefinite in reciting “diagnosing *P. aeruginosa*”

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because it is not clear how a kit can be used for diagnosing a bacterium, or what is precisely involved in the process of “diagnosing *P. aeruginosa*” as usually what is “diagnosed” using a kit is a disease, and infection, or a clinical condition caused by a microbial pathogen, but not a bacterial pathogen itself. *See Office Action* § 20(a). Claims 18, 20 and 36 have been amended to refer to “diagnosing *P. aeruginosa* infection.” In light of this clarification, Applicants respectfully request that the rejections of claims 18, 20 and 36 under 35 U.S.C. § 112, second paragraph be withdrawn.

The Examiner has also alleged that claim 9 is vague and indefinite in the recitation “fragment of said second protein” because what constitutes a “fragment” and how much of the second protein’s original structure has to be retained such that the resulting product can be considered as a “fragment” is not clear. *See Office Action* § 20(b).

Applicants respectfully disagree. The test for definiteness under 35 U.S.C. § 112, second paragraph is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). *See also* MPEP § 2173.02. The specification as originally filed makes clear that any such fragments must be antigenic fragments. For example, page 2, lines 12-23 of the specification as originally filed describe varying the sequence of fragments while retaining antigenic properties and testing said fragments for antigenicity. Additionally, page 3, lines 6, 13, 20, 25, 32 and 34 of the specification as originally filed all refer to the use of “antigenic fragments” in embodiments of the invention. It would be clear to one skilled in the art, reading the claims in light of the specification, that enough of the second protein’s original structure must be retained in the fragment so as to render the fragment

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antigenic. Therefore, the rejection of claim 9 under 35 U.S.C. § 112 should be withdrawn.

Claims 22, 25, 27 and 36 depend from claim 9 and were also rejected as being similarly indefinite. For at least the reasons stated above, Applicants respectfully request that the rejections of claims 9, 22, 25, 27 and 36 under 35 U.S.C. § 112, second paragraph be withdrawn.

The Examiner has further alleged that lines 3 and 4 of claim 37 fail to distinctly claim the subject matter of the invention in the limitation “said fragment comprises an N-terminal amino acid sequence of.” *See Office Action* § 20(c). This limitation of claim 37 has been amended to read “said antigenic fragment comprises at its N-terminus, the amino acid sequence of [SEQ ID NO:2.” As such, Applicants respectfully request that the rejection of claim 37 under 35 U.S.C. § 112, second paragraph be withdrawn.

#### **IV. CONCLUSION**

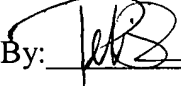
In view of the foregoing amendments and remarks, Applicants respectfully request withdrawal of the outstanding rejections and allowance of the pending claims.

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Applicants do not believe that any fee, other than a three-month extension fee, is required in connection with the submission of this document. However, should any additional fee be required, or if any overpayment has been made the Commissioner is hereby authorized to charge any fees, or credit any overpayments, to Deposit Account 02-4377. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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